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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,891	10/15/2003	Amir J. Tehrani	RMXLNZ00100	7544

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EXAMINER	
ALTER, ALYSSA MARGO	
ART UNIT	**PAPER NUMBER**
3762	
MAIL DATE	**DELIVERY MODE**
09/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,891	TEHRANI, AMIR J.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *123-127,141,142 and 149-158* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *123-127,141,142 and 149-158* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 17, 2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 123-127, 141-142 and 149-158 have been considered but are not persuasive. The claims have been amended to include the stimulation signal is delivered to the "diaphragm or phrenic nerve tissue" as well as "in response to sensed respiration due to phrenic nerve activity". These amendments are considered functional language and introductory statement of intended use. Therefore, the claims remain rejected under Ignagni et al. as detailed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 123-127, 141-142 and 149-158 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission

amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements in claims 123, 126 and 153 are: the elements that perform the sensing of the respiration due to phrenic nerve activity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 123-127, 141-142 and 149-158 are rejected under 35 U.S.C. 102(e) as being anticipated by Ignagni et al. (US Patent Publication 20050021102 A1). Ignagni et al. discloses conditioning a diaphragm by delivering electrical stimulation to the target site in the diaphragm tissue to cause the diaphragm to contract.

The “electrical stimulation of the diaphragm can be synchronized with attempts at breathing or breathing made by the patient (e.g., on the patient's own or by the mechanical ventilator). For example, electrical stimulation can be triggered following the inspiration phase of the breath (i.e., during exhalation) to maximize the contraction during the period when the diaphragm is at its longest length"(page 4, paragraph 38). Therefore, the diaphragm stimulation affected intrinsic breathing and thus elicits an

inspiration and exhalation duration and rate different from the intrinsic inspiration and exhalation duration and rate.

Additionally, the functional language and introductory statement of intended use of claims 123, 126 and 153 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Ignagni et al. utilizes a stimulator as claimed by the Applicant, Ignagni et al. is therefore capable of being used in response to sensed respiration from phrenic nerve activity. In addition nothing prevents Ignagni et al. from employing the stimulation after sensed respiration from phrenic nerve activity. Therefore, the stimulator is capable of dispensing stimulation after sensed respiration due to phrenic nerve activity.

Also, the functional language and introductory statement of intended use of claims 149-150 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Ignagni et al. utilizes a stimulator as claimed by the Applicant, Ignagni et al. is therefore capable of being used to deliver a signal to the tissue to elicit a slow elongated inspiration or a fast, short inspiration In addition nothing prevents Ignagni et al. from eliciting these types of breaths. Therefore, the Ignagni et al. is capable of administering stimulation to elicit a slow elongated inspiration or a fast, short inspiration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 123-127, 141-142 and 149-158 rejected under 35 U.S.C. 102(b) as anticipated by Scheiner et al. (US 6,415,183) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scheiner et al. (US 6,415,183) in view of Meer (US 4,830,008). Scheiner et al. discloses at least one sensor configured to sense respiratory information and at least one electrode coupled to the tissue in order to stimulate the tissue to elicit a diaphragm response. This stimulation therapy sequence is depicted in figure 4. Scheiner et al. also discloses the employment of an IPG in order to respond to the sensed signals and deliver stimulation to the electrodes. Additionally, the electrical stimulation of the diaphragm would obviously control or affect the rate of inspiration and the rate of exhalation, since the stimulation dispensed affects respiration.

The functional language and introductory statement of intended use of claims 123, 126 and 153 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Scheiner et al. utilizes a stimulator as claimed by the Applicant, Scheiner et al. is therefore capable of being used in response to sensed respiration from phrenic nerve activity. In addition nothing prevents Scheiner et al. from employing the stimulation after sensed respiration from phrenic nerve activity. Therefore, the stimulator is capable of dispensing stimulation after sensed respiration due to phrenic nerve activity.

Also, the functional language and introductory statement of intended use of claims 149-150 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Scheiner et al. utilizes a stimulator

as claimed by the Applicant, Scheiner et al. is therefore capable of being used to deliver a signal to the tissue to elicit a slow elongated inspiration or a fast, short inspiration In addition nothing prevents Scheiner et al. from eliciting these types of breaths. Therefore, the Scheiner et al. is capable of administering stimulation to elicit a slow elongated inspiration or a fast, short inspiration.

Although the examiner considers Scheiner et al. to disclose a stimulator capable of dispensing stimulation after sensed respiration due to phrenic nerve activity, in the alternative, Scheiner et al. discloses the device substantially as claimed except for the sensing of the phrenic nerve. Meer teaches that it is well known to sense the electrical activity of the phrenic nerve in order to determine respiratory information. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a sensor to sense phrenic activity into the phrenic nerve stimulation system as disclosed by Scheiner et al. in order to provide the predictable results of reducing the amount of implanted leads and sensors.

Furthermore, such a modification to the system to include one sensing/stimulating electrode would have been obvious to one having ordinary skill in the art at the time the invention was made since it was known in the art of implantable medical devices to employ sensing/stimulating electrodes in order to reduce the amount of implanted leads and sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
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